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APPLICATION NO.-	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,324	12/01/2003	Joseph Hare	10008.0113US01 (HA68-002)	3654
44305	7590	01/03/2007	EXAMINER	
WITHERS & KEYS, LLC P. O. BOX 2049 MCDONOUGH, GA 30253			JACKSON, BRANDON LEE	
			ART UNIT	PAPER NUMBER
			3772	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/726,324	<b>Applicant(s)</b> HARE ET AL.	
	<b>Examiner</b> Brandon Jackson	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/1/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/1/2003 and 11/15/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "42" has been used to designate both "second region" and "aperture" in fig. 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

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informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: "31" on page 6, line 10 should be "13."

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "a/the second portion" in claim 6, lines 4 and 2.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-4, 6, 15, 17-18, 25-26, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/298,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention of application claim 1 is broader than the invention of patent application 11/298,251 claims 1 and 5 of the patent application 11/298,251. The covering of the instant invention of application is equivalent to the drape of patent application 11/298,251. With respect to claim 2, all the limitations can be found in claims 1 and 5 of patent application 11/298,251. With respect to claim 3, all the limitations can be found in claim 2. With respect to claim 4, all the limitations can be found in claim 4 of patent application 11/298,251. With respect to claim 6, all the limitations can be found in claim 9 of patent application 11/298,251. With respect to claim 15, all the limitations can be found in claim 8 of patent application 11/298,251. With respect to claim 17, all the limitations can be found in claims 18-20 of patent application 11/298,251. With respect to claim 18, all the limitations can be found in claims 18-20 of patent application 11/298,251. With respect to claim 25, all the limitations are found in claims 18-20 of patent application 11/298,251. With respect to claim 26, all the limitations are found in claims 18-20 of patent application 11/298,251. With respect to claim 29, all the limitations are found in claims 1, and 5.

Claims 5 and 7-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-2, 1-5, of copending Application No. 11/298,251 in view of Grier-Idris (U.S. Patent 5,197,493) and

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Levitt et al. (U.S. Patent Application 2002/0108615). The patent application 11/298,251 substantially discloses claims 1-4, see provisional rejection above, however patent application 11/298,251 fails to disclose a cellulosic substrate, a second region and portion made of the same material, and first and second portions made of the same material. Grier-Ildris teaches a first (26) and second (14) portions made of cellulosic material, and Levitt teaches a second region (12) is made of cellulosic material.

Polymeric film is being interpreted as cellulosic material in accordance with the Merriam-Webster Dictionary definition attached. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to substitute the material of the covering for the materials, as taught by Grier-Ildris and Levitt, because of cellulosic material's absorbent properties to remove fluid from the treatment site.

Claims 19-20, 22, and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18-20 of copending Application No. 11/298,251 in view of Grier-Ildris (U.S. Patent 5,197,493) and Levitt et al. (U.S. Patent Application 2002/0108615). The patent application 11/298,251 substantially discloses claims 17 and 18, see provisional rejection above, however patent application 11/298,251 fails to disclose a cellulosic substrate, a second region and portion made of the same material, and first and second portions made of the same material. Grier-Ildris teaches a first (26) and second (14) portions made of cellulosic material, and Levitt teaches a second region (12) is made of cellulosic material. Polymeric film is being interpreted as cellulosic material in accordance with the Merriam-Webster Dictionary definition attached. Therefore it would be obvious to one of

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ordinary skill in the art at the time of the invention to substitute the material of the covering for the materials, as taught by Grier-Ildris and Levitt, because of cellulosic material's absorbent properties to remove fluid from the treatment site.

Claims 10-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/298,251 in view of Grier-Ildris (U.S. Patent 5,197,493) and Keusch et al. (U.S. Patent 5,225,236). The patent application 11/298,251 substantially discloses the invention's claims, see claim 1, 2, and 6 provisional rejection above, however patent application 11/298,251 fails to disclose the first and second portion materials. Grier-Ildris teaches a first portion made of polymeric film (col. 1, lines 14-16), and Keusch teaches a second portion made of a viscoelastic hydrophilic gel (col. 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the device with the materials, as taught by Grier-Ildris and Keusch, because of hydrophilic gel's absorbent properties to remove fluid from the treatment site.

Claims 21 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of copending Application No. 11/298,251 in view of Grier-Ildris (U.S. Patent 5,197,493) and Keusch et al. (U.S. Patent 5,225,236). The patent application 11/298,251 substantially discloses the invention's claims, see claims 17-19 provisional rejection above, however patent application 11/298,251 fails to disclose the first and second portion materials. Grier-Ildris teaches a first portion made of polymeric film (col. 1, lines 14-16), and

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Keusch teaches a second portion made of a viscoelastic hydrophilic gel (col. 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the device with the materials, as taught by Grier-Idris and Keusch, because of hydrophilic gel's absorbent properties to remove fluid from the treatment site.

Claim 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of copending Application No. 11/298,251 in view of Lavender et al. (U.S. Patent 5,562,107). Patent application 11/298,251 substantially discloses the invention's claims, see claim 17 provisional rejection above, however patent application 11/298,251 fails to disclose a first adhesive region strength that is greater than the second adhesive region strength. Lavender teaches a hinged wound covering device (10) that has two layers of adhesive that allow the cover to be opened without removing the device from the patient (col. 1-2, lines 66-67, 1-9). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention was made to modify the adhesive strengths of the cover device of patent application 11/298,251 with that of Lavender, because adhesive of Lavender is used to allow the device to open and reseal without accidentally removing the device from the patient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 9, 15-20, 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gries-Idris (U.S. Patent 5,197,493). Grier-Idris discloses an incise system (10), comprising a flexible substrate defining an aperture permitting selective access to an aseptic treatment site (fig. 3), a transparent cover borne by the substrate (col. 1, lines 14-16) and which is irremovably affixed in aseptic covering relative to the aperture (fig. 3), a first (10) and second (11) region selectively detachable (col. 3, lines 13-19) wherein the second region (11) comprises a disposable sterile drape. The drape is presumed to be sterile because modern surgical drapes are inherently sterile to prevent unnecessary infections. Perforations surround the first region (10) and allow for the first region (10) to be separated from the second region (11). The first region (10) has a first portion (26) that defines the fenestration, and a second portion (14) detachable from the second region (11), wherein the first (26) and second (14) portions are made of the same polymeric material (col. 1, lines 14-16). The transparent cover (col. 1, lines 14-16) defines a cavity over the aseptic treatment site (50) relative to the

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fenestration (26), and the transparent cover (col. 1, lines 14-16) does not contact the aseptic treatment site (fig. 4). The device has a first adhesive region (24) is borne on the second surface (22), and a second adhesive region (40) borne by the flexible transparent cover (col. 1, lines 14-16). The device can be adhesively fixed to the patient (col. 2, lines 12-15), and the transparent cover (col. 1, lines 13-19) can be moved from the covering to the uncovering position without detaching the device from the patient (col. 5, lines 36-43), because the first adhesive strength is greater than the second adhesive strength (col. 5, lines 36-43).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5, 7, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grier-Idris (U.S. Patent 5,197,493) in view of Levitt et al. (U.S. Patent Application

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Publication 2002/0108615). Grier-Ildris substantially discloses the invention's claims; see claims 1, 2, 6, and 16-19 rejections above, however Grier-Ildris fails to disclose a second region and second portion comprising the same material nor that the material is cellulosic. Levitt teaches a drape (12) made of polymeric film. Examiner is interpreting the polymeric film of the drape (12) to be made of a cellulosic material, since according to the Merriam-Webster Dictionary cellulosic acetate is defined as a polymeric film. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the material of the drape disclosed by Grier-Ildris for the polymeric film, as taught by Levitt, because of hydrophilic gel's absorbent properties to remove fluid from the treatment site.

Claims 8, 10-14, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Grier-Ildris (U.S. Patent 5,197,493) in view of Keusch et al. (U.S. Patent 5,225,236). Grier-Ildris substantially discloses the invention's claims; see claims 1, 2, 6, 10 and 16-19 rejections above, and first and second surface of a hinged transparent cover (fig. 3) to the first portion (26) and able to be moved in a substantially arcuate path (fig. 3). The first portion (26) is releasably bonded to the patient over the fenestration (26). However, Grier-Ildris fails to disclose a second region fabricated from a different material. Keusch teaches a drape fabricated from a viscoelastic hydrophilic gel (col. 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Grier-Ildris drape material for the viscoelastic hydrophilic gel, as taught by Keusch, because of hydrophilic gel's absorbent properties to remove fluid from the treatment site.

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Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grier-Ildris (U.S. Patent 5,197,493) in view of Wiedner et al. (U.S. Patent 5,538,012). Grier-Ildris substantially discloses the invention's claims; see 17-19 rejections above, however Grier-Ildris fails to disclose first and second portion made of different materials. Wiedner teaches a first portion (5) made of an absorbent material, and a second portion (4') made of siliconized paper. Therefore, it would have been obvious to one of ordinary skill in the art at the time in the invention to substitute the material of the surgical device of Grier-Ildris for the material, as taught by Wiedner, because of the non-absorbent properties of siliconized paper.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dowdy (U.S. Patent 5,975,082), Veras (U.S. Patent Application 2003/0009122), Burkoth (U.S. Patent Application 2003/00113827), Hathman (U.S. Patent 5,702,356).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

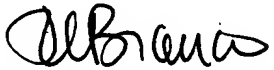
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson  
Examiner  
Art Unit 3772

BJ

  
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